EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedures
for
Preparation and Review of Antimicrobial Testing Program Disinfectant Performance Reports

SOP Number: ADM-01-02

Date Revised: 04-25-05

Prepared By: _____ Date: ___/___/___

Print Name:_____

Reviewed By: _____ Date: ___/___/___

Print Name:_____
Technical Staff

_____ Date: ___/___/___

Print Name:_____
QA Officer

_____ Date: ___/___/___

Print Name:_____
Laboratory Director

Date Issued: ___/___/___

Withdrawn By: _____ Date: ___/___/___

Controlled Copy No.: _____

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1.0 SCOPE AND APPLICATION:

1.1 This protocol describes the procedures for the preparation and quality assurance review of Performance Reports for disinfectant products testing under the Antimicrobial Testing Program (ATP).

2.0 DEFINITIONS:

2.1 Performance Report = A report documenting the efficacy test on a disinfectant when tested by the prescribed method. The final performance report contains information referred to in Section 10.0.

2.2 ATP = Antimicrobial Testing Program

2.3 BRA = Biological Report of Analysis

2.4 COC = Chain of Custody

2.5 GLP = Good Laboratory Practices

2.6 MLB = Microbiology Laboratory Branch

2.7 OECA = Office of Enforcement and Compliance Assurance

2.8 OPP = Office of Pesticide Programs

3.0 HEALTH AND SAFETY: None

4.0 CAUTIONS: None

5.0 INTERFERENCES:

5.1 Incomplete paperwork and documentation can impede the report process and may impact further regulatory action.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel responsible for the preparation and review of final performance reports are required to be knowledgeable of the procedures in this SOP.

7.0 SPECIAL APPARATUS AND MATERIALS: None
8.0 INSTRUMENT OR METHOD CALIBRATION: None

9.0 SAMPLE HANDLING AND STORAGE: None

10.0 PROCEDURE AND ANALYSIS:

10.1 In summary, the Performance Report consists of the BRA's, the Study Protocol, Test Parameters, GLP Statement, Analyst Signature Page, the Standard Data Summary Sheets, copies of test information sheets, chain-of-custody documentation, and copies or photocopies of actual product labels.

10.2 Components of a typical Disinfectant Performance Report:

10.2.1 The performance report will be compiled within a reasonable amount of time after completion of an efficacy evaluation of a product. An efficacy evaluation involves testing of a product as specified in an ATP Study Protocol. The performance report, which is assembled in a binder, will consist of but is not limited to the following:

Title Page
Table of Contents
GLP Statement
Study Protocol and Attachments
Test Analyst Signature Page
Signature form for Personnel
Data Summary Sheets
Test Information Sheets
Chain of Custody (Documentation for Samples Tested)
Photocopy or photograph of product label on sample container

10.2.2 Accompanying the performance report is (are) the Biological Report(s) of Analysis (es) (EPA Form 8510-14) and the QA Statement.

10.3 Review of Draft Reports:

10.3.1 The laboratory test coordinator or assigned report coordinator will assemble the draft report in a binder and check it for completeness.

10.3.2 A QC Checklist will be filled out and a copy sent with the Performance Report to the Study Director/designee for review.

10.3.3 The Study Director/designee will peer review the report for errors and completeness, sign off on the QC checklist and return the draft

report to the test coordinator or the assigned report coordinator who will incorporate any additional corrections/changes.

10.4 Quality Assurance Officer Review of Draft Performance Report:

10.4.1 After completion of the draft report and all subsequent corrections/changes, the draft performance report along with the QC checklist and all supplemental documents will be sent to the OPP Microbiology Laboratory Quality Assurance Officer (QAO).

10.4.2 The QAO will review the draft report for completeness and determine whether additional revisions/corrections are necessary.

10.4.3 If errors are noted by the QAO, the QAO will either submit a memo outlining the revisions/corrections necessary for the report or notations will be made in the draft report and returned to the test coordinator or the assigned report coordinator.

10.4.4 The test coordinator or the assigned report coordinator will ensure all required revisions/corrections are completed by the appropriate analyst. The QAO will verify that all corrections or required revisions have been made during review of the Final Report.

10.4.5 The QAO review process of the draft report will be repeated, as necessary until no additional changes are required by the QAO.

10.5 Preparation and Deposition of the Final Report

10.5.1 Once all of the changes to the draft report have been made, the test coordinator or the assigned report coordinator will prepare a Final Performance Report.

10.5.2 The Final Performance Report will include original signed copies of the GLP statement and the Test Coordinator signature page as well as original page stamps.

10.5.3 Original Page Stamps will be place on each page of the Final Performance Report beginning at the “Table of Contents.” The page stamp includes the page number, the EPA Reg. Number and the type of test performed.

10.5.4 Appropriate personnel involved in any aspect of the product

evaluation will sign the BRA(s).

10.5.5 Upon completion of the all copies of the final performance report, the draft report and the finalized performance report will be submitted to the QAO. The QAO will review the final performance report against the draft report.

10.5.6 The QAO will complete a final review of the Performance Report and if satisfied, will attach a signed and dated QAO Statement which will be inserted before page 1 of the final performance report.

10.5.7 Two additional photocopies of the original report will be prepared from the original page stamped final performance report.

10.5.8 The final performance report with original signatures and the two photocopies will be sent to the Branch Chief of the Microbiology Laboratory Branch (MLB).

10.5.9 The Branch Chief will review the final performance report and will sign and date the BRA(s). One copy of the final report and BRA(s) will be kept in the MLB's archive file room.

10.5.10 The final performance report with original signatures will be sent to OECA. A copy of the report with a transmittal memo will be sent to the Antimicrobials Division.

10.5.11 A chemical analysis of the product will be performed by the OPP Analytical Chemistry Branch (ACB) and a report sent to the Antimicrobials Division under separate cover.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Completed reports are archived in secured cabinets in the file room. Only authorized personnel have access to the file room. Data are subject to OPP's official retention schedule (see ADM-03).

13.0 QUALITY CONTROL:

13.1 The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good

Laboratory Practices. Appropriate quality control measures are integrated into each SOP.

13.2 Study Protocols are tracked in the Master Schedule which is maintained electronically.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any nonconformance will be documented and appropriate corrective action will be implemented.

15.0 REFERNCES: None.

16.0 FORMS AND DATA SHEETS:

16.1 QC Checklist

Report Preparation and QC Checklist

OPP Microbiology Laboratory

Product Name: _____ EPA Reg. No.: _____

Sample No(s).:_____

Test(s) Performed:_____

Report Paperwork	Compiled By/Date:	Reviewed By/Date: Team Leader	QA Officer	Revisions Made By/Date:	Final Report Reviewed by/Date:
Title Page					
Table of Contents					
GLP Statement					
Study Protocol					
Test Coordinator Page					
Staff Signature Page					
Summary Data Sheet(s)					
Test Information Sheets					
Test Data Sheets					
Carrier Count Data/Dilution Scheme					
Confirmation Sheets					
Worksheets					
Lab's COC Documentation					
Inspector's COC Documentation					
Product Sample Label(s)					
BRA(s)					
Media/Reagents Prep Sheets (check only)					
Other:					

Apply N/A (not applicable) where necessary.